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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,909	06/11/1999	JON A. WOLFF	MIRUS.011.01	1001

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/330,909

Applicant(s)

WOLFF ET AL.

Examiner

Joseph Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,12-14,16-18 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,12-14,16-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This application is an original application, filed June 11, 1999, which claims benefit to provisional application 60/100,168, filed September 14, 1998.

Applicants' amendment filed May 3, 2002, paper number 19, has been received and entered. Claims 3, 15 and 19 have been canceled. Claims 1, 4, 18 and 20 have been amended. Claims 1, 2, 4-6, 12-14, 16-18 and 20-22 are pending and currently under examination.

Response to Amendment

The declaration filed on May 3, 2002, paper number 20, under 37 CFR 1.131 is sufficient to overcome the rejection made under 35 USC 102(a) over the Hajjar *et al.* reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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Claims 1, 2, 4-6, 12-14, 16 and 17 rejected under 35 U.S.C. 102(a) as being clearly anticipated Hajjar *et al.* is withdrawn.

As noted above, the declaration filed under 37 CFR 1.132 is sufficient to obviate the use of the Hajjar *et al.* reference.

Claims 1, 2, 4-6, 12-14, 16-18, and 20 stand rejected under 35 U.S.C. 102(e) as being anticipated by Isner *et al.* (US patent # 5,830,879).

Applicants note that the claims have been amended to recite 'injecting' in place of 'introducing'. Applicants argue that Isner *et al.* '879 teach the direct contact of the nucleic acid with the vessel wall in contrast to the instantly claimed method. See Applicants' amendment, top of page 4. Applicants' arguments have been fully considered but not found persuasive.

As noted previously, Isner *et al.* teach a variety of types of catheters for the delivery of a polynucleotide to cardiac tissue. It is noted that Isner *et al.* consistently use the term 'contact' however it does not appear that specific examples discussed by Isner *et al.* were meant to be limiting to contacting a DNA coated catheter balloon to the surface of the vessel. For example Isner *et al.* teach that 'the nucleic acid can be delivered by any means of administration' (column 2, line 24). Further, in listing and describing the various catheters and means of delivery, Isner *et al.* specifically teach a hydrogel coated balloon and differentiate it from other types of balloon catheters (column 2, lines 25-29; column 6, lines 21-30). Examiner would concede that a preferred embodiment in certain situations for delivery taught by Isner *et al.* is a polymer coated

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catheter comprising DNA (column 6; lines 31-32), however, it does not appear the Isner *et al.* exclude the delivery of a polynucleotide by means normally affected by balloon catheters. To the contrary, in specifically differentiating the various types of catheters, in particular a polymer coated balloon, and referencing the use of said catheters by methods previously known and used in the art (column 6; lines 25-29), it appears that Isner *et al.* contemplate the instantly claimed methodology.

Therefore, for the reasons above and of record, the rejection is maintained.

Claims 1, 2, 4-6, 12-14, 16-18, and 20 stand rejected under 35 U.S.C. 102(e) as being anticipated by Mann *et al.* (US patent # 5,922,687).

Applicants summarize the teaching of Mann *et al.* noting that the process of Mann *et al.* comprises an invasive procedure which results on applying pressure to the target cells. In contrast to the devices used by Mann *et al.* Applicants argue that the instantly claimed process uses the living tissue as the pressurized enclosure subjecting them to mechanical stress, and that the claims have been amended to more clearly set forth Applicants process. See Applicants' amendment, middle of page 4. Applicants' arguments have been fully considered but not found persuasive.

Upon review of the present specification for means of delivery specifically contemplated, various means and devices known in the prior art are specifically taught and contemplated (page 13; lines 16-20). Examiner notes that the methods of Mann *et al.* are not specifically disclosed in

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the present specification, however, the claims as written clearly do not exclude any mechanical means to affect the invention. Further, in light of the teaching of the present specification, any device in the prior art would appear to be contemplated for use in the instantly claimed methods. As noted previously, Examiner would agree that the methods taught by Mann *et al.* is an invasive means to increase the permeability of a cell, however, given the general guidance for the delivery of a polynucleotide and teachings for use of 'electroporation' and use of "'biolistic" or "gun" techniques' (specification, page 13; lines 16-20), the instantly claimed methods can reasonably be interpreted to encompass any means or device previously described, including invasive techniques. Additionally, it is noted that Mann *et al.* do teach alternative means not requiring a sealed apparatus, for example the method using a catheter for delivery (Figure 4C-single balloon catheter). In view of the open language of the instant method claims and the general teaching of the instant disclosure, the claimed method is not limited to any specific means of introducing a nucleic acid into a blood vessel or delivering the nucleic acid to a heart muscle cell.

Thus, for the reasons above and of record, the process disclosed by Mann *et al.* anticipates the claimed invention because it includes all the method steps recited in the claims, therefore, the rejection is maintained.

Claims 1, 2, 4-6, 12-14, 16-18 and 20-22 stand rejected under 35 U.S.C. 102(a/e) as being anticipated by Wolff *et al.* (US Patent 5,693,622).

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Applicants note that the claims have been amended to clarify the claimed process as it is directed to injecting the nucleic acid into a blood vessel. Applicants note and argue that Wolff *et al.* '622 teach injecting nucleic acid directly into the muscle. See Applicants' amendment, bottom paragraph on pages 4. Applicants' arguments have been fully considered but not found persuasive.

Examiner agrees that Wolff *et al.* does teach the direct injection of a nucleic acid into the muscle of the heart, however a review of the disclosure provides teaching that the nucleic acid can be delivered by a variety of means, including "introduction into the circulation" (column 6, lines 4-9). It is noted that Wolff *et al.* do not specifically disclose the delivery of a polynucleotide to cardiac tissue through a vein or artery, however this form of delivery to a tissue is generally supported as noted above, and in a more specific example for the delivery of a polynucleotide to the pancreas (column 15, lines 1-11). In the section specifically teaching dosage and route of administration, Wolff *et al.* do not exclude any form of delivery or teach that any route would be favored over another except that the dose and route would depend on condition and size of the subject (column 20, lines 33-44). With specific reference to the heart and cardiac therapies, Wolff *et al.* indicated that they chose 'to focus on delivery to the myocardium' however, 'that this should not be interpreted as a limitation' (column 40, lines 1-8). Clearly Wolff *et al.* contemplate various routes of delivery and specifically disclose administration of a nucleic acid to a vessel for the delivery to the cells of the pancreas. In view of the teachings of Wolff *et al.* as a whole, Applicants' arguments are not persuasive because

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there is nothing in Wolff *et al.* which would lead one to exclude the delivery of a nucleic acid with a catheter to cardiac tissue. Examiner would concede that a catheter can be used for the delivery of a composition directly into muscle, however there is no teaching in Wolff *et al.* which would exclude the conventional use of a cardiac catheter for the delivery a compound intervascularly. Because the instant claims require only the injecting the nucleic acid into a heart vessel, the methods taught by Wolff *et al.* anticipated the claims.

Thus, for the reasons above and of record, the teachings of Wolff *et al.* provide the necessary guidance which would anticipate the instantly claimed invention, and therefore, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach


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